

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 283 to 305 are pending in the application, with claims 283, 291, and 298 being the independent claims. Claims 221 to 282, in addition to previously canceled claims, are sought to be canceled without prejudice to or disclaimer of the subject matter therein. Applicants reserve the right to pursue the subject matter of these claims in related applications. Claim 283 is identical to canceled claim 281. Claims 284 to 305 are new. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

New Claims 283 to 305

New claims 283 to 305 are directed to the soluble extracellular portion of TNFR-5. Support for these claims may be found throughout the application as filed. Furthermore, support for these claims may be found throughout U.S. Provisional Application No. 60/035,496, filed January 14, 1997 ("the first priority document"), for example: at page 121 (claim 19), page 21, lines 1-4 and 15-19; page 38, lines 1-13, and Example 1a for claims 283 and 284; at page 29, lines 19-24, page 30, lines 11-20, page 31, lines 20-25, and page 32, lines 15-25 for claim 291; and at page 6, lines 14-24; and page 38, lines 1-22 for claim 298.

As clearly stated in the specification of the present application, as well as in the specifications of U.S. Provisional Application No. 60/054,885, filed on August 7, 1997

("the second priority document"), and the first priority document, the soluble extracellular portion of TNFR-5 has a well-established utility, or alternatively an asserted utility, which is specific, substantial, and credible, as an inhibitor of apoptosis. The first priority document clearly and unambiguously defines an "antagonist" as "naturally occurring and synthetic compounds *capable of inhibiting apoptosis*" (first priority document at page 51, lines 29-30, emphasis added), and further notes that "[a]ntagonist can include soluble forms of TNFR . . ." (first priority document at page 51, lines 24-25; *see also* first priority document at page 54, lines 28-30). Example 5, pages 65-66 of the present application, demonstrates experimentally that the soluble extracellular domain of TNFR-5 indeed inhibits apoptosis, *i.e.*, acts as an "antagonist" as defined in the first priority document. Accordingly, as of January 14, 1997, Applicants had established a specific, substantial, and credible utility for the soluble extracellular domain of SEQ ID NO:2 or variants thereof, as recited in claims 283 to 305.

Priority Determination

The Examiner maintains the contention that the first priority document does not meet the requirements of 35 U.S.C. §§101 and 112, because the specification allegedly does not establish utility for SEQ ID NO:2 according to the current Utility Examination Guidelines, Fed. Reg. 66(4) at 1092-1099 (2001). The Examiner argues that "none of the asserted utilities require[] any feature or activity that is specific to the disclosed TNFR-5." Paper No. 06092004 at page 4. Again, Applicants respectfully traverse.

In addition to authority cited herein, Applicants continue to rely on the authority cited in the Amendment and Reply filed on March 22, 2004.

First of all, the Examiner's arguments focus on the physiological function of a TNF type receptor (see, e.g., Paper No. 06092004 at page 5). The Examiner's focus is misplaced, because the claims are not directed to "a TNF type receptor," but rather, to the soluble extracellular domain of SEQ ID NO:2, for which Applicants have clearly asserted a substantial, specific, and credible utility as discussed herein.

Applicants recognize that a claimed invention must possess either a well-established utility or an asserted utility that is specific, substantial and credible. *See* Guidelines, 66 Fed. Reg. at 1098. If the claimed invention has an asserted utility that is specific, substantial and credible utility, or a well-established utility exists for the invention and a utility rejection is improper. *See* "Revised Interim Utility Guidelines Training Materials" (Utility Guidelines), page 9, and more specifically Example 8 at pages 45 and 46. In Example 8, "compound A" is stated to inhibit enzyme XYZ, a well known enzyme. The model claim 1 is directed to "Compound A." *Id.* at page 45. The example explains that since inhibition of enzyme XYZ is a "well established utility," a rejection of model claim 1 under 35 U.S.C. § 101 would be improper. *Id.* at page 46.

Similarly to claims to "compound A," claims 283 to 305 of the present application recite the soluble extracellular domain of TNFR5 or variants thereof, which is disclosed in inhibit apoptosis. As noted above, the first priority document discloses that soluble forms of TNFR inhibit apoptosis, and further discloses a variety of diseases or conditions where inhibition of apoptosis would be desirable. Furthermore, apoptosis is a well-known biological function, and inhibition of apoptosis is not a property applicable to a general class of compounds. Indeed, even beyond Applicants' assertions, it was well established in the art that inhibition of apoptosis would be desirable in various "real world" contexts. Finally, based on the totality of evidence and the

reasoning provided in the first priority document, and as borne out in Example 5 of the present application, one of ordinary skill in the art would clearly have found this utility believable. Thus, as with "compound A" described in Example 8, the soluble extracellular domain of TNFR5 was shown in the first priority document to have a well-established utility, or alternatively an asserted utility, which is specific, substantial, and credible. Accordingly, as with the claim to "compound A" in Example 8, it is improper for the Examiner to make a rejection of the subject matter of claims 283 to 305 under 35 U.S.C. § 101.

For the reasons discussed above regarding utility under 35 U.S.C. § 101, Applicants further assert that the first priority document further meets the requirements of 35 U.S.C. § 112, first paragraph with respect to the presently claimed invention. The Examiner "should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. 101 rejection is proper." M.P.E.P. § 2107.01 at 2100-36. Therefore, since the first priority document complies with the utility requirement of 35 U.S.C. § 101 with respect to the pending claims, the rejection under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn.

For the reasons discussed above, Applicants respectfully assert that pending claims in the present application are clearly entitled to the benefit of the filing date of provisional application No. 60/035,496 under 35 U.S.C. § 119(e). Accordingly, acknowledgement of priority to January 14, 1997 is respectfully requested.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 117-220 under 35 U.S.C. § 102(e) as allegedly being anticipated by Ashkenazi *et al.*, U.S. Patent Application Publication No. 2002/0161202 ("the '022 publication"). Based on Applicants' arguments regarding priority, *supra*, Applicants respectfully traverse. Claims 221-282 have been canceled, claims 283-305 are pending. As discussed above, Applicants are entitled to claim priority to the first priority document, filed January 14, 1997 under 35 U.S.C. § 119(e). Accordingly, the effective filing date for the pending claims presented herein is January 14, 1997. Thus, the '022 publication, the earliest possible effective filing date of which is June 18, 1997, cannot anticipate the pending claims.

Based on these remarks, Applicants respectfully request that the 102(e) rejection be reconsidered, and further, that it be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes", is written over the printed name.

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